under 35 U.S.C. § 112. In addition, the following remarks address the Examiner's rejections under 35 U.S.C. § 102(b), as well as the other issues raised in the Office Action of June 22, 1999.

Objection to the Specification

The Examiner has objected to the Specification because "Figures 7A-7C are not described" in the Brief Description of the Drawings. The Specification has been amended to more clearly describe Figures 7A and 7B; there is no Figure 7C in the drawings. No new matter has been added by this amendment.

Claim Rejection – 35 U.S.C. § 112

Claims 1-10, 20, 50 and 52-59 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. According to the Examiner, in Claim 20 it is unclear how the first catheter is inserted into its own first catheter lumen. Claim 20 has been amended to clarify that the first catheter is inserted into the lumen of the aspiration catheter, not the first catheter. In Claim 50, the "in" in the first line has been corrected to read "is" as requested by the Examiner.

In Claims 1 and 52, the Examiner stated that it is unclear how the expandable device inhibits migration, and how the fluid pressure inhibits migration. As discussed at the October 22, 1999 interview, Applicant has amended the claims in accordance with suggestions recommended by the Examiner to place these claims in condition for immediate allowance. Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. § 112 be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 1-14 and 52-59 have been rejected under 35 U.S.C. § 102(b) as anticipated by Simpson et al. According to the Examiner, Simpson et al. discloses a method of inserting a catheter having an occlusive device at its distal end distal of the stenosis. A sealed treatment area is created and therapy is performed on the occlusion. The fluid pressure prevents any loose particles from flowing out of the treatment area, and the particles are removed by aspiration.

Simpson et al. discloses a catheter device for creating a sealed treatment chamber surrounding a treatment site. The catheter is inserted to the desired site in the patient, and the two expandable sealing members located on the catheter are inflated to form a fluid seal within the walls of the blood vessel and create the isolated treatment chamber. The sealing members prevent particles from migrating out of the area, and keep fluid from inside the vessel outside of

B

the sealed treatment area. Treatment is performed on the friable material within the chamber using a blade located on the device, and infusion of a fluid from outside the patient's body is performed through a lumen within the catheter, followed by aspiration through the catheter.

By contrast, Claim 1 recites a method of treatment of a blood vessel in which blood fluid flows proximally to distally, said method comprising:

> delivering an expandable device to form a barrier sufficient to inhibit emboli suspended in said fluid from migrating past the barrier in a proximal to distal direction;
>
> preventing emboli from moving in a distal to proximal direction by exposing said expandable device to blood fluid pressure within said vessel;
>
> advancing a catheter having a lumen in fluid communication with a distal opening in the catheter, said advancing comprising moving said distal opening relative to said expandable device within the blood vessel such that said opening is distal to at least a portion of an occlusive substance within said blood vessel, said occlusive substance comprising said emboli suspended in said fluid;
>
> drawing fluid from the vessel into the distal opening such that (a) a fluid flow is created in the lumen in a distal to proximal direction, and (b) said fluid flow is simultaneously created in said vessel in a proximal to distal direction, whereby said emboli are carried by said fluid flow from said vessel into said distal opening and through said lumen of said catheter.

Similarly, Claim 52 recites a method of treatment of a blood vessel in which blood flows proximally to distally, said method comprising:

> delivering an expandable device to form a barrier sufficient to inhibit emboli suspended in said blood from migrating past the barrier in a proximal to distal direction;
>
> preventing emboli from moving in a distal to proximal direction by exposing said expandable device to blood flowing in a proximal to distal direction;
>
> advancing a catheter having a lumen in fluid communication with a distal opening in the catheter, said advancing comprising moving said distal opening relative to said expandable device within the blood vessel such that said opening is distal to at least a

B

portion of an occlusive substance within said blood vessel, said occlusive substance comprising said emboli suspended in said blood;

drawing blood from the vessel into the distal opening such that (a) a blood flow is created in the lumen in a distal to proximal direction, and (b) said blood flow is simultaneously created in said vessel in a proximal to distal direction, whereby said emboli are carried by said blood flow from said vessel into said distal opening and through said lumen of said catheter.

delivering an expandable device to form a barrier sufficient to inhibit emboli suspended in said fluid from migrating past the barrier in a proximal to distal direction;

preventing emboli from moving in a distal to proximal direction by exposing said expandable device to blood fluid pressure within said vessel;

Simpson teaches a sealed chamber in which there is no blood flow. Accordingly, Simpson does not teach or suggest the methods claimed herein in which emboli are prevented from moving in a distal to proximal direction by exposing an expandable device to blood flowing in a proximal to distal direction. Accordingly, Applicant respectfully submits that Claims 1 and 52, and all claims dependent therefrom, are allowable over Simpson.

Furthermore, the device in Simpson would be wholly incapable of movement of the distal opening of a catheter until it is proximal to an occlusive substance during the drawing of fluid into the distal opening. This is because the expandable sealing members of Simpson create a fixed treatment chamber. In Simpson, the catheters are in a fixed location by sealing the balloons on the distal end of the catheters to the walls of the vessel. By contrast, Claim 12 recites a method for the evacuation of emboli from a blood vessel comprising:

positioning a catheter having a lumen in fluid communication with a distal opening in the catheter such that said opening is distal to at least a portion of an occlusive substance within said blood vessel, said occlusive substance comprising said emboli suspended in fluid;

drawing fluid from the vessel into the distal opening such that emboli are carried by said fluid flow from said vessel into said distal opening and through said lumen of said catheter; and

moving the distal opening in the catheter until it is proximal to said occlusive substance during the drawing of fluid into the distal opening.

Accordingly, Applicant respectfully submits that the rejection of Claim 12 and all claims dependent therefrom be withdrawn.

Double Patenting Rejection

Claims 1-59 have been rejected under the judicially created doctrine of double patenting over Claims 1-42 of U.S. Patent Application No. 08/049,857. In a telephone conversation with Applicant's representative AnneMarie Kaiser on August 6, 1999, the Examiner clarified that the rejection was intended to be given over U.S. Patent Application No. 08/813,807, the parent application, and not the present application. In addition, the Examiner stated that since the parent application has been abandoned, the rejection was not proper and will be withdrawn. Such action is respectfully requested.

Conclusion

The present application is now in condition for allowance and such action is respectfully requested. Should the Examiner have any remaining concerns that could be resolved by telephone, she is invited to contact the undersigned attorney at the telephone number appearing below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Dec. 3, 1999

By: _____

Sabing H. Lee
Registration No. 43,745
Attorney of Record
620 Newport Center Drive
Sixteenth Floor
Newport Beach, CA 92660
(949) 760-0404